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|----------------------------------|------------------|----------------------------------------------|-------------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/815,562 | 03/31/2004 | Mohamed Zaiou | 15670-076001 / 2002-119 | 5767 |
| 41790 7: | 590 02/03/2006 | | EXAM | INER |
| 200011111 | INGERSOLL LLP | MITRA, RITA | | |
| (INCLUDING | BURNS, DOANE, SW | | | |
| 12230 EL CAMINO REAL | | | ART UNIT | PAPER NUMBER |
| SUITE 300 SAN DIEGO, CA 92130 | | | 1653 | |
| | | | DATE MAILED: 02/03/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--|--|--|--|
| | Application No. | Applicant(s) | | | | |
| | 10/815,562 | ZAIOU ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Rita Mitra | 1653 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D/ - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>01 D</u> | ecember 2005. | | | | | |
| ·= · · · · · · · | action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | nce except for formal matters, pro | secution as to the merits is | | | | |
| closed in accordance with the practice under E | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) <u>1-21</u> is/are pending in the application. 4a) Of the above claim(s) <u>1,2 and 11-21</u> is/are | _ | | | | | |
| 5) Claim(s) is/are allowed. · | Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>3-10</u> is/are rejected. | Claim(s) <u>3-10</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) acc |))☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correct | = , , | • • | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152. | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. ☐ Certified copies of the priority documents | | | | | | |
| 2. Certified copies of the priority documents | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| • • | application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| dec the diabled detailed embe determined a lieu | · | ,u. | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) X Notice of References Cited (PTO-892) | 4) Interview Summary | (PTO-413) | | | | |
| 2) D Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Da | ate | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/1/2005,4/25/2005 | 5) Notice of Informal F 6) Other: | atent Application (PTO-152) | | | | |
| | | | | | | |

DETAILED ACTION

Status of the Claims

Applicants' response to restriction requirement dated September 28, 2005, filed on December 1, 2005, is acknowledged. Applicants have elected, without traverse Group III, claims 3-10 and SEQ ID NO: 2 for examination. Claims 1, 2 and 11-21 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on December 1, 2005. Therefore, claims 3-10 are currently under examination.

Claim rejection - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is vague and indefinite because it is drawn to non-elected embodiments. The election without traverse was to the peptide of claim 3(b), "a peptide comprising a sequence as set forth in SEQ ID NO: 2 from about amino acid 31-131". Fragments, equivalents and variants are non-elected subject matter confound the claims. Limiting the claims to the elected sequence would be sufficient to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Boman et al. (WO 96/08508, March 21, 1996). The reference teaches new polypeptides (FALL-39) and functional derivatives thereof; pharmaceutical composition containing said polypeptides; a method for inhibiting microbial growth in animals including human; and a cDNA sequence capable of expressing a precursor protein to such polypeptide (see abstract, page 1, Examples 1, 2, 5, Fig 1, 4, 5). Boman's polypeptide has 100% sequence identity to the amino acid sequence of SEQ ID NO: 2 (31-131) of instant application (see sequence alignment result 4, Database:

A_Geneseq_21, Accession NO: AAR92924), thus anticipating claims 3, 6, 7, 8, 9, 10. The reference further shows in Example 5 that Fall-39 is active against *Bacillus megaterium* (gram positive, claim 4) and *Escherichia coli* (gram negative, claim 5). Thus Boman et al. anticipates claims 3-9 of instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boman et al. (WO 96/08508)

The teachings of Boman et al. (WO 96/08508) with respect to the polypeptide solution have been discussed above. In addition at page 6, line 35+, Boman et al. (WO 96/08508) disclose that the solution comprising the polypeptide can be used to lavage internal organs. Lavage could

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only be performed if the infected organ is treated topically, even if the surface to be treated is on the inside of a cavity or tube. Hence, it is *prima* facie obvious to topically administer the polypeptide-containing solution.

Conclusion

No claims are allowable.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita Mitra whose telephone number is 571-272-0954. The examiner can normally be reached on M-F, 10:00 am-7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the

Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita Mitra, Ph.D.

January 23, 2006

✓ JON WEBER

SUPERVISORY PATENT EXAMINER